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INTRAOCULAR PRESSURE REDUCTION
AND REGULATION SYSTEM

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INTRAOCULAR PRESSURE REDUCTION AND REGULATION SYSTEM

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Introduction

The National Aeronautics and Space Administration (NASA) both by law and policy works to share widely the results of its research and development. NASA conducts an active agencywide technology transfer program using a variety of ways to make aerospace-related technology available for other uses. One of the ways used to help transfer technology is to join with others in selected technology application projects such as the Intraocular Pressure Reduction and Regulation System Project.

Background

Dr. William J. McGannon, a prominent ophthalmologist in the Cleveland area, came to the NASA Lewis Research Center a few years ago and suggested an application project to transfer technology to the development of a cataract surgical tool. Lewis initiated such a project, and as a part of the work on the cataract tool, a flow compensating pressure regulator was developed. The regulator was designed to maintain reasonable intraocular pressure control during widely varying fluid flow conditions associated with the use of the tool. It was felt, particularly by Dr. McGannon, that this pressure regulator might provide major benefits in other types of eye surgery. In particular, he was interested in evaluating the regulator as a means to reduce before surgery the intractable high intraocular pressure associated with some glaucoma cases.

Based on the proposed use, the regulator equipment was modified slightly to provide the capability to set the regulator to a desired pressure and to controllably reduce that pressure over a selected time period.

A simple laboratory unit was assembled and given preliminary evaluation on both a laboratory test chamber and on excised animal eyes. A separate method (fig. 1) of artificially raising the intraocular pressure of excised animal eyes was devised so that it was possible to evaluate

the performance of the pressure regulator system both in matching and reducing intraocular pressures.

The pressure reduction and regulation system was first demonstrated to Drs. John and Randall Bellows of Chicago who encouraged continuing the work. The system was described and demonstrated to Dr. Dong Shin of Kresge Eye Institute who worked intensively with the unit both in Cleveland and in Detroit. Dr. Shin has from that time on been directly involved with Dr. McGannon in the further development, refinement, and evaluation of the system.

The first public presentation of the system took place at the International Glaucoma Congress II in Miami Beach, Florida, January 29, 1978.

SYSTEM

Function

A fluid supply whose pressure has been matched to the existing intraocular pressure is connected to the anterior chamber of the eye through a small cannula inserted near the edge of the cornea (fig. 2). The pressure of the fluid supply is reduced in a controlled fashion and in such a way that the intraocular pressure is reduced by the same amount and at the same rate until the pressure reaches the minimum value specified by the doctor. Subsequently, the desired minimum intraocular pressure is maintained during the surgical procedure. Lastly, the system also functions to markedly reduce the dynamic intraocular pressure fluctuations that result from surgical manipulation of the eye. A separate intraocular pressure measuring and recording system is used in laboratory work; its other use is entirely optional.

Description

The system is most easily described by reference to figure 3. An elevated liquid source provides the input pressure for the system as well as meeting any fluid flow demands of the surgical procedure. The fluid from the elevated source flows through an air-water separator device and then into the lower part of a flow compensating pressure regulator. The output pressure of the regulator is preset using a spring adjustment to a selected minimum pressure that is desired to be maintained in the eye (e.g., 10 mm Hg).

A vertical tube or standpipe is connected to the top of the regulator and is filled with a column of distilled water to provide an additional

regulator pressure bias. The level of the column of liquid is selected to that the total output pressure of the regulator (that is, the set desired minimum pressure plus the liquid column level) equals the existing intraocular pressure. Silicone tubing runs from the output of the pressure regulator to a corneal infusion fitting. Insertion of the corneal fitting connects the anterior chamber of the eye to the external fluid system. Because the existing intraocular pressure and the external fluid pressure have been matched, the existing intraocular pressure is temporarily maintained. The column of distilled water is now slowly drained from the vertical standpipe to reduce fluid system pressure at a controlled rate. Intraocular pressure is reduced in the same amount and at the same rate. When the standpipe has been fully drained, intraocular pressure has been reduced to the value previously specified by the doctor and set on the pressure regulator spring adjustment (e.g., 10 mm Hg).

In order to accomplish the reduction of intraocular pressure, an extremely small amount of intraocular fluid must flow out of the eye. The basic outflow path to permit this flow is a small bleed line attached to the infusion fitting short distance from the eye. The pressure regulator also incorporates a relief valve as a backup, but all outflow is normally through the small bleed line.

Intraocular pressure can be continuously recorded if desired either by connecting to the line to the cannula or through a separate small second cannula. Both methods are accurate for steady-state and low-flow conditions; the two cannulae method is required to measure dynamic pressure fluctuations accurately.

The corneal infusion fitting is connected by two small silicone tubes to a feed fitting (fig. 4), and the feed fitting is in turn connected to the liquid output of the pressure regulator. The feed fitting is normally attached to the plastic surgical drape during surgery to reduce pull and torque on the infusion fitting. The feed fitting incorporates the small bleed line, and the top of the feed fitting is a thin silicone diaphragm. This diaphragm acts as a shock absorber to reduce the dynamic intraocular pressure excursions that result from manipulating the eye during the course of eye surgery.

The corneal infusion fitting (fig. 5) contains a firmly positioned knife within it to cut the required carefully sized incision at the limbus. The cannula has a small lip around its perimeter to retain the unit in the incision. Once the knife and the cannula have penetrated the cornea, the infusion fitting is held by a forceps and the knife is removed, thus opening the infusion fitting to the anterior chamber. The corneal fitting has a seal within it that seals the knife opening as the knife is withdrawn. The infusion fitting has been designed to minimize the trauma of insertion, to provide a secure snug fit, and to provide the mechanism for matching intraocular and external pressures.

The pressure regulator (fig. 6) is a flow compensating device that senses changes in flow by means of a flow sensing diaphragm and adjusts its pressure output accordingly so as to maintain the desired minimum intraocular pressure over a wide range of flow rates resulting from surgical penetration of the eye. An adjustable external orifice permits adjusting the regulator to accommodate different surgical tools with various fluid flow characteristics. The presently used corneal infusion fitting is equivalent to a 21 gauge needle and permits flow up to 50 milliliters per minute. This maximum flow rate of the infusion fitting, not regulator capacity, is the limiting factor in maintaining intraocular pressure to accommodate the flow demand from various surgical penetrations of the eye.

The entire system is made of materials suitable to be sterilized by autoclaving. All tubing is silicone; the basic regulator and related parts are polysulfone with some small parts of polyimide. Very few metal parts are used; however, the infusion needle and knife are stainless steel, and some internal regulator parts are either titanium or monel.

It should be noted that if only very small liquid flows and variations in flow are expected during the surgery and after surgical penetration of the eye, intraocular pressure can be established and maintained by setting and regularly adjusting pressure (i.e., height) of the fluid supply alone, and the pressure regulator need not be part of the system. Such a simplified system where pressure is controlled by adjusting the height of a bag of fluid has, however, certain operating drawbacks: for example, a bag low enough to provide the desired minimum pressure does not have sufficient pressure "muscle" to adjust quickly to changes in demand.

A photograph of the actual system is shown in figure 7.

Performance

Dr. Shin has requested that this paper include information illustrating the performance of the intraocular pressure reduction and regulation system in both laboratory and clinical use. Accordingly, this section very briefly covers selected data representative of (1) laboratory evaluations at Lewis Research Center where the system was tested with both a simple fluid test chamber and a large number of excised animal eyes, (2) using the system in a variety of tests with live animals at Kresge Eye Institute, and (3) using the system in a few selected clinical cases at Harper Hospital.

Figure 8 shows, for a small test chamber, the simple reduction of pressure from an elevated to a desired lower level over a selected time period. Also for this

small test chamber, figure 9 shows dynamic pressure excursions resulting from the rapid application and release of an external load. The load is applied by a cam-driven mechanical arm for precise repeatability and is identical in all cases. The two curves at the left are of a closed test chamber at two different bases, or resting pressures. The curve to the right is with the intraocular pressure reduction and regulation system connected to the test chamber and shows the substantial damping effect of the system on dynamic pressure excursions. The curve to the right also shows the small, short time duration, negative excursion below resting pressure that accompanies the reduction on the positive pressure peaks. This negative excursion is a measure of recovery time of the system in restoring the desired minimum pressure under the test conditions.

The animal work (fig. 10) was performed in the Kresge Eye Institute animal laboratory with anaesthetized live rabbits.

The data presented in figure 11 confirm in a live eye the damping effect of the intraocular pressure reduction and regulation system on dynamic pressure excursions from external loads. Under condition A the eye is at a stable resting pressure of about 10 mm Hg with a pressure recording cannula only inserted; that is, the intraocular pressure reduction and regulation system is not in use. External loads are applied to the cornea with a handheld ophthalmodynamometer. At point (1) a 50-gram load was applied, at point (2) a 30-gram load, and at points (3) and (4) a 20-gram load. Condition B has the same eye at the same stable resting pressure of about 10 mm Hg but with the intraocular pressure reduction and regulation system cannula inserted and the system in use. A 20-gram load is applied at points (10) and (11), a 30-gram load at points (12) and (13), and a 50-gram load at points (14) and (15). A reduction of the dynamic increase in intraocular pressure resulting from external load is clearly apparent in a comparison of the excursions under conditions A and B.

The clinical case (fig. 12) is of a selected individual undergoing a trabeculectomy procedure. Note that a separate cannula is used for pressure recording to provide an accurate record of the rapid dynamic changes as well as the slower changes in intraocular pressure. The intraocular pressure recording (fig. 13) of the trabeculectomy procedure has certain points noted:

- (1) Insertion and manipulation of the lid retractor
- (2) Conjunctival dissection
- (3) Scleral flap dissection
- (4) Pressure reduction and regulation system activated

(5) Intraocular penetration with desired minimum set pressure maintained.

(6) Scleral flap and conjunctival closing

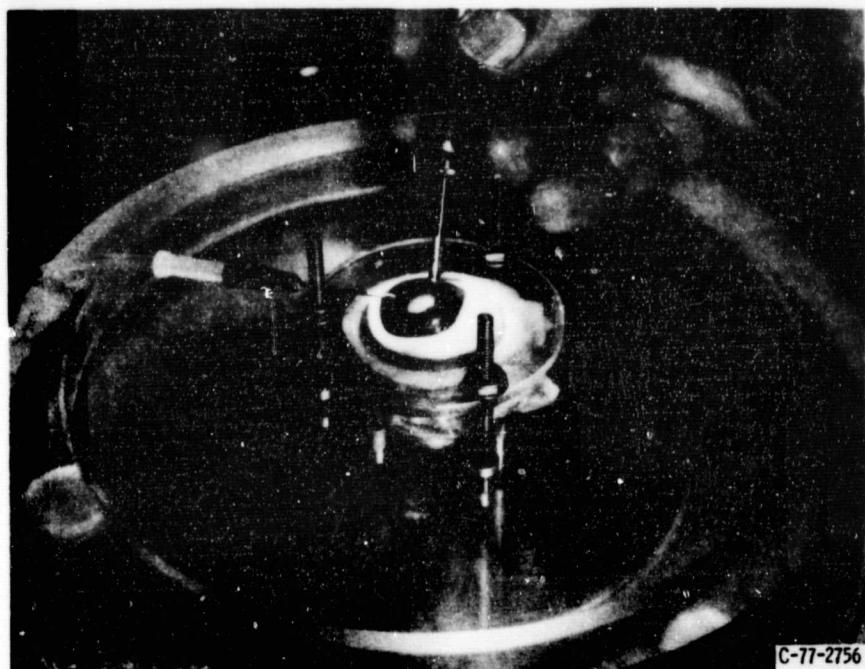
(7) Surgery complete, equipment removed

The section marked (4) in figure 12 shows both the reduced intraocular pressure excursions and the slow decrease in the resting intraocular pressure (from about 25 to about 12 mm Hg) as requested by the surgeon.

One or some combination of the functions of the pressure regulator system may be useful in various types of eye surgery; Dr. Shin is considering a program to investigate several possible clinical applications. In this connection he asked that intraocular pressures be recorded (record only, not regulate) during an enucleation procedure. This was done, and the pressure recording (figure 4) shows the very large excursions that can be experienced during enucleation with maximum pressures well in excess of 400 mm Hg. It is expected that future work will include evaluating the performance of the intraocular pressure reduction and regulation system in reducing these extreme pressure excursions.

SUMMARY

The intraocular pressure reduction and regulation system provides certain specific functions: it can be used to lower (or raise) intraocular pressure in a controlled way; it responds rapidly to maintain a selectable set, minimum intraocular pressure under variable flow demands; and it reduces the rapid dynamic increases in intraocular pressure resulting from loads applied to the eye. The system has been tested and evaluated in the laboratory with a small test chamber and with excised animal eyes and subsequently with anaesthetized live animals. The system has also had limited clinical use with selected cases. An expanded program of laboratory and clinical investigations is planned.



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Fig. 1. - Device for holding animal eye and artificially raising intraocular pressure.

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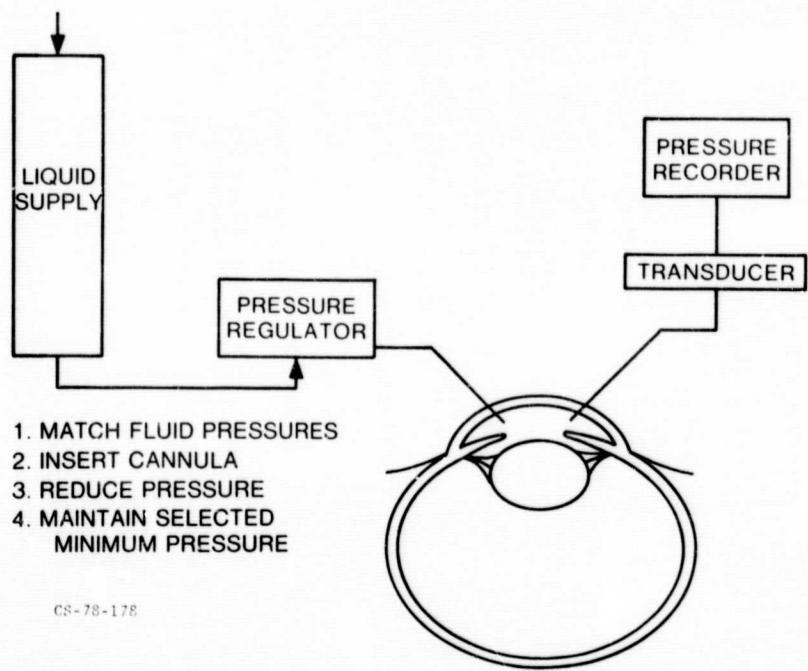


Fig. 2. - External fluid supply connected to anterior chamber of eye.

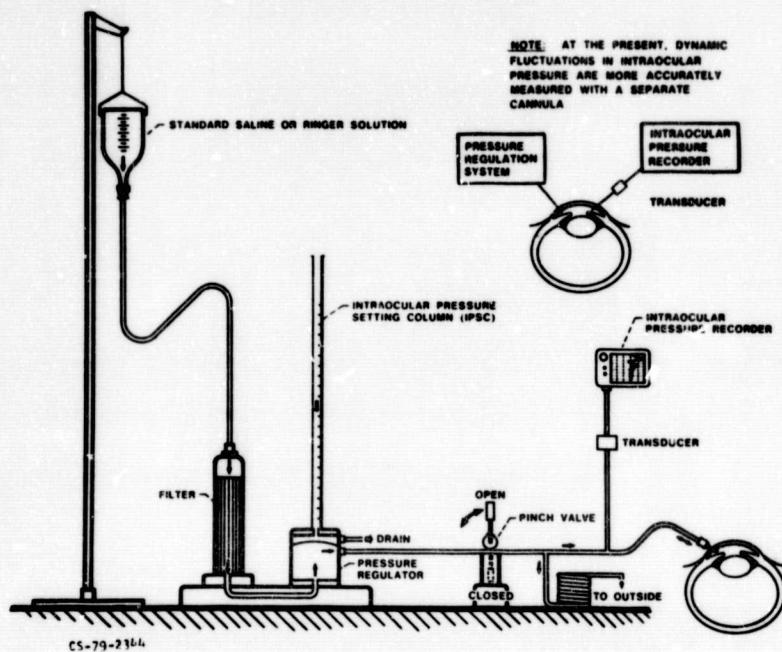


Fig. 3. - Diagram, intraocular pressure reduction and regulation system.

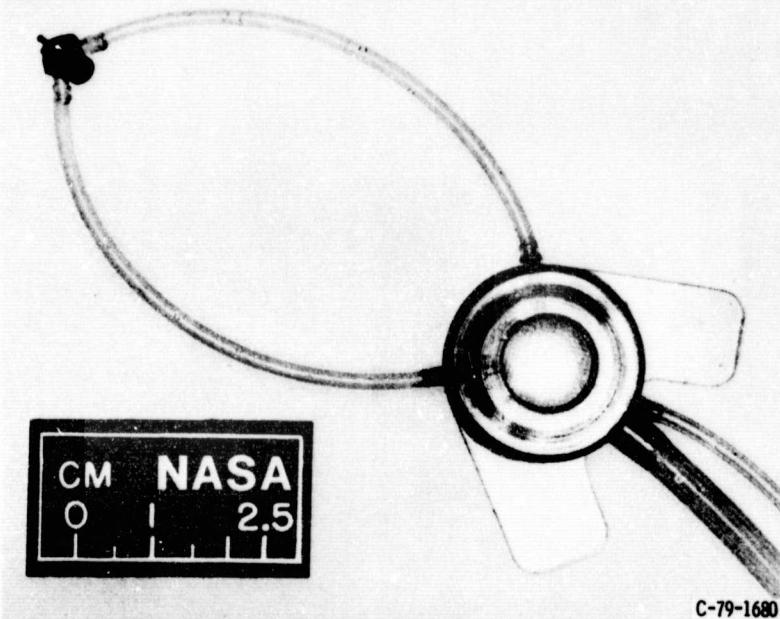


Fig. 4. - Arrangement, feed fitting and corneal infusion fitting.

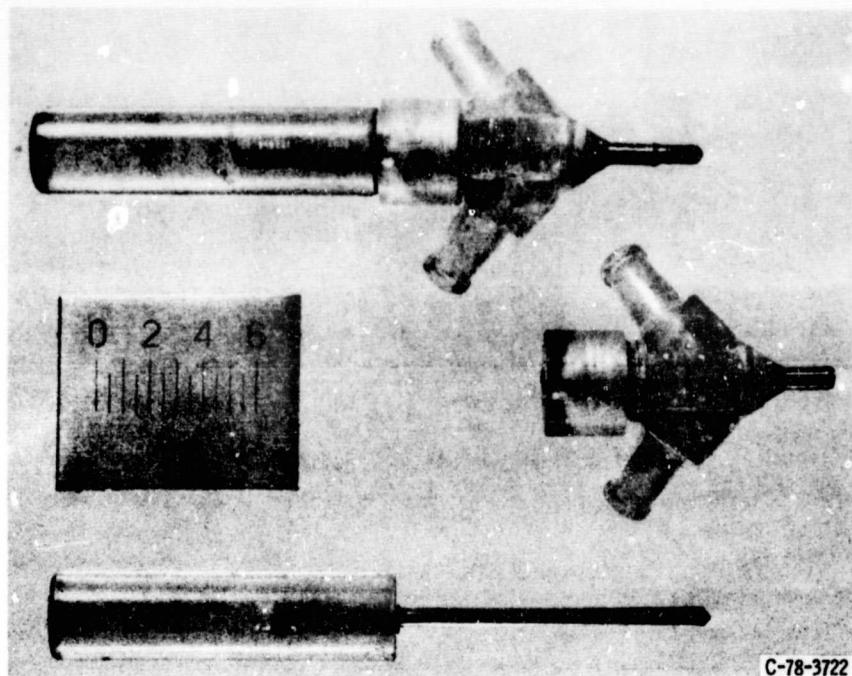


Fig. 5. - Corneal infusion fitting.

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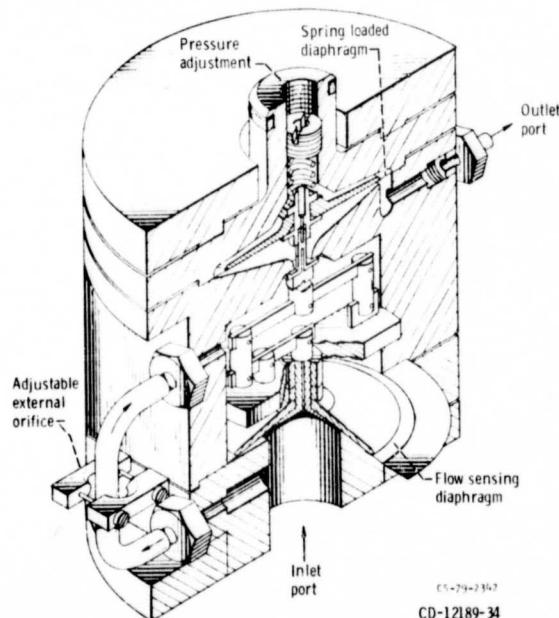


Fig. 6. - Flow compensating pressure regulator.

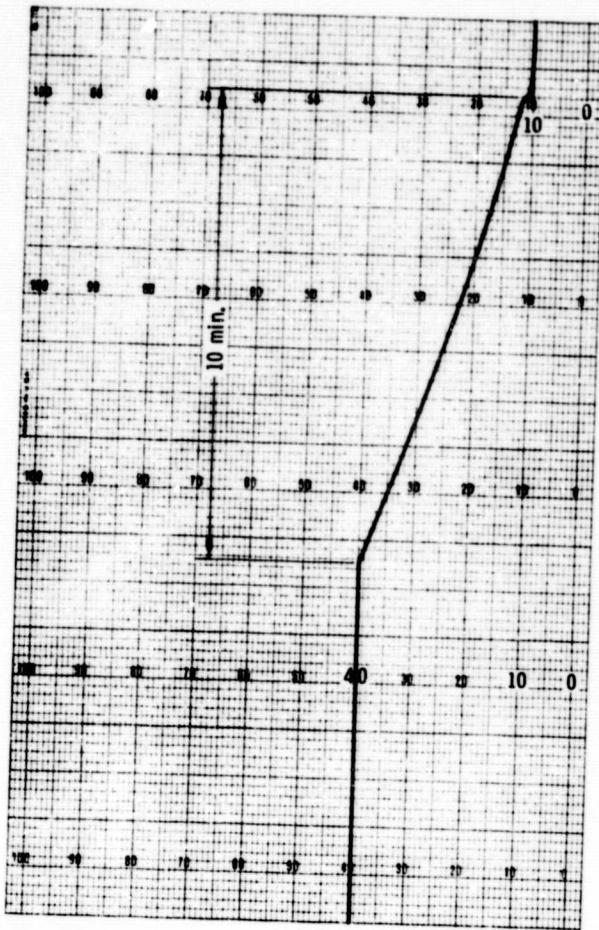


Fig. 8. - Test chamber pressure reduction to specified minimum level.

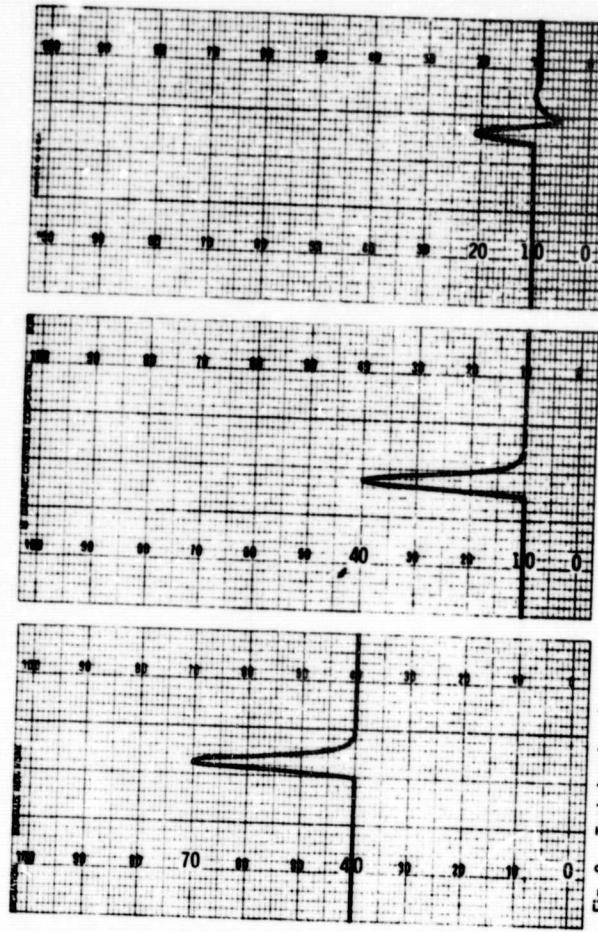
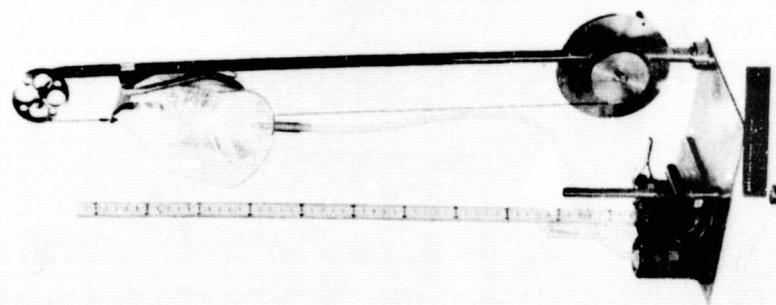


Fig. 9. - Test chamber dynamic pressure response to same applied external load; two curves at left are closed chamber, curve at right is with intraocular pressure reduction and regulation system connected.



C-79-1681

Fig. 7. - Intraocular pressure reduction and regulation system.

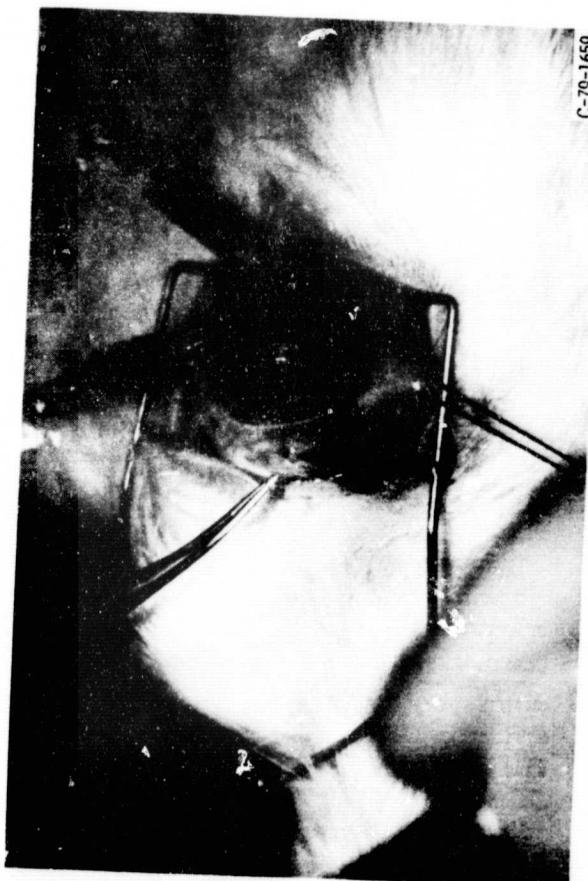


Fig. 10. - Rabbit eye with intraocular pressure reduction and regulation system and intraocular pressure recording connected.

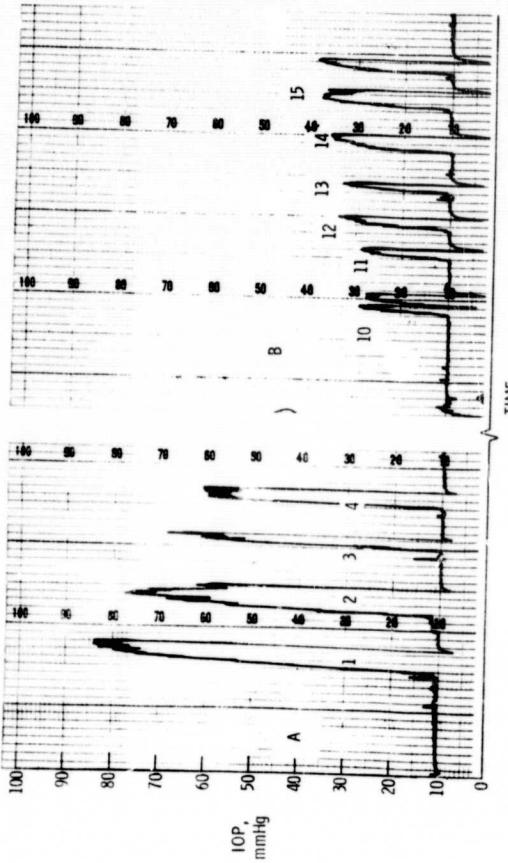


Fig. 11. - Laboratory data, pressure excursions from external loads, live eye.



Fig. 12. - Clinical trabeculectomy, intraocular pressure reduction and regulation system and intraocular pressure recording connected.

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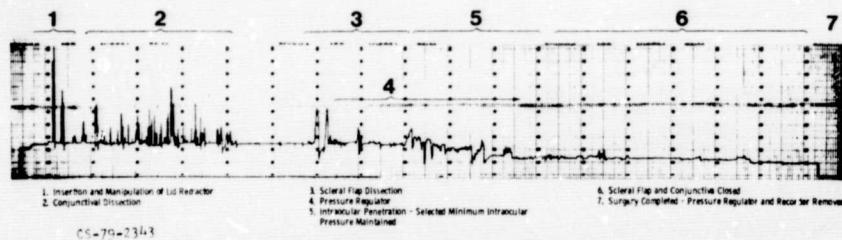


Fig. 13. - Record of intraocular pressure, trabeculectomy procedure.

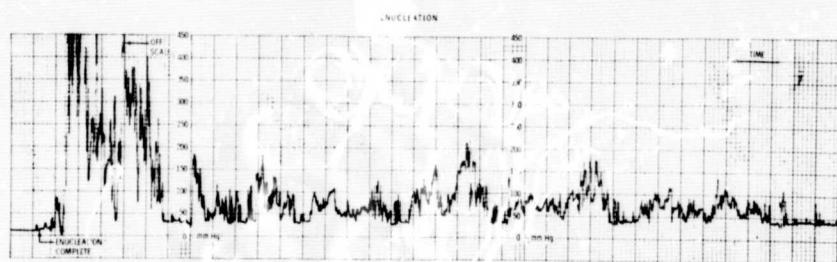


Fig. 14. - Record of intraocular pressure, enucleation procedure (recording right to left).